510(k) SUMMARY K130234 p1/3

Nuvon Vitals Charting System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

MAR 1 3 2013

4801 South Broad Street, Suite 120
Building 100 Innovation Center
Philadelphia, PA 19112
Phone: 1-484-319-7345
Facsimile:
Contact Person: John R. Zaleski
Date Prepared: Thursday, January 17, 2013

Name of Device and Name/Address of Sponsor

Nuvon Vitals Charting System
Nuvon, Inc.
4801 South Broad Street, Suite 120
Philadelphia, PA 19112

Common or Usual Name

Physiological and biomedical device data retrieval and display system and rules engine and standard industry format (e.g.: XML, HL7) translator.

Classification Name/Product Code/CFR Reference

Monitor, Physiological, Patient (Without Arrhythmia Detection)
Product Code: MWI
CRF Reference: 870.2300

Predicate Device(s)

VISICU ARGUS, K012171
Airstrip Remote Patient Monitoring Viewing System, K121871

Intended Use / Indications for Use

The Nuvon Vitals Charting System is an accessory to the Nuvon VEGA System (K103125) and is intended to display patient information and surveillance of monitored patients at the point of care location

and at a remote supplementary care location through wide area networking technology. The Nuvon Vitals Charting System is only intended to display physiologic and other patient information and intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitored devices from which it obtains its data. The Nuvon Vitals Charting System is not intended for monitoring purposes, nor is it intended to control any of the biomedical devices and information systems with which it interconnects.

Technological Characteristics

The Nuvon Vitals Charting System is a software only system that permits the display of data from biomedical, patient care devices, and ancillary hospital systems (e.g.: laboratory and hospital admission, discharge and transfer systems). The system can be used to review and validate the data for transfer to existing hospital information technology and electronic medical record systems. Additionally, the system can be used for patient surveillance to evaluate trends in patient data.

Performance Data

Validation and verification of the Nuvon Vitals Charting System performance focused on the following areas:

- unit testing, in which functions are verified for valid function and operate per requirements and design;
- integration and system testing, in which functions operate within the scope of the larger system, in this case, the operation of Nuvon Vitals Charting with respect to the overall VEGA System;
- performance or non-functional testing, in which the operation of the product to support multiple simultaneous users and demonstrate key functional performance over time so as to illustrate it can scale to meet multiple user operation without appreciable degradation in performance. Results of verification and validation activities have shown that the Nuvon Vitals Charting System displays biomedical device data communicated from the source devices through the system in a manner consistent with the expected performance.

Substantial Equivalence

The Nuvon Vitals Charting System is substantially equivalent to the VISICU ARGUS System and the Airstrip Patient Monitoring System. The Nuvon Vitals Charting System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Nuvon Vitals Charting System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Nuvon Vitals Charting System meets its specifications and intended use, and thus is substantially equivalent performance to the VISICU ARGUS System and the Airstrip Patient Monitoring System. Thus, the Nuvon Vitals Charting System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Nuvon, Inc.
c/o Mr. Jonathan Kahan
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K130234
Trade/Device Name: Nuvons Vital Charting System
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: January 30, 2013
Received: January 30, 2013

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130234

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Nuvon Vitals Charting System

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2013.03.13
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